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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,154	09/23/2003	Avram Scheiner	279.608US1	1665
21186	7590	03/27/2006	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH 1600 TCF TOWER 121 SOUTH EIGHT STREET MINNEAPOLIS, MN 55402			HELLER, TAMMIE K	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/669,154	Applicant(s) SCHEINER, AVRAM	
	Examiner Tammie Heller	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 6, 8-13, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheiner et al. (U.S. Patent No. 6,415,183), herein Scheiner. Regarding claims 1, 8, and 11, Scheiner discloses a method and apparatus for diaphragmatic pacing which includes ventricular sensing and shock channels (see col. 3, ln. 59-60 and col. 4, ln. 3-7), a controller (see col. 5, ln. 63-67 and col. 6, ln. 1-3), and thoracic impedance and diaphragmatic pacing channels (see col. 5, ln. 65-67 and col. 6, ln. 1-3). Further, the controller of Scheiner is programmed to deliver a shock pulse when ventricular fibrillation is detected and deliver a diaphragmatic pacing pulse when no respiratory activity is detected (see col. 6, ln. 9-14 and 19-21).

3. Regarding claim 2, Scheiner discloses that the diaphragmatic pacing channel may also be used to deliver cardiac pacing pulses (see col. 4, ln. 7-9).

4. Regarding claims 3 and 13, Scheiner discloses that the diaphragmatic pacing pulse is on the order of 0.2 to 14 volts (see col. 4, ln. 62-65), which is within the range of 10 to 30 volts.

5. Regarding claims 6, 10, and 16, Scheiner discloses that a diaphragmatic pacing pulse may be delivered during a ventricular refractory period after a ventricular sense (see col. 9, ln. 29-30).

6. Regarding claim 9, Scheiner illustrates in Figure 7 that a diaphragmatic pacing pulse may be delivered during ventricular fibrillation while the device prepares to deliver a shock pulse.

7. Regarding claim 12, Scheiner discloses that the diaphragmatic pacing is delivered as pacing pulses to the phrenic nerve (see col. 3, ln. 43).

8. Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Casavant et al. (U.S. 2004/0088015), herein Casavant. Regarding claims 1, 8, and 11, Casavant discloses an implantable medical device for diaphragmatic stimulation which includes ventricular sensing and shock channels (see paragraph 28, ln. 4-10 and paragraph 48, ln. 12-14), a controller 114 (see paragraph 6, ln. 1-3 and paragraph 57, ln. 1-4), and thoracic impedance and diaphragmatic pacing channels (see paragraph 16 and paragraph 48, ln. 12-14). Further, the controller of Casavant is programmed to deliver a shock pulse when ventricular fibrillation is detected and deliver a diaphragmatic pacing pulse when no respiratory activity is detected (see paragraph 66 and paragraph 94, ln. 7-15).

9. Regarding claim 2, Casavant discloses that the diaphragmatic pacing channel may also be used to deliver cardiac pacing pulses (see paragraph 48, ln. 11-12).

10. Regarding claims 3 and 13, Casavant discloses that the diaphragmatic pacing pulses may be applied at an amplitude of 20 volts (see paragraph 59, ln. 9-10), which is within the range of 10 to 30 volts.

11. Regarding claims 4, 9, and 14, Casavant discloses that the controller begins charging an output capacitor of the ventricular shock channel when ventricular fibrillation is detected and a diaphragmatic pacing pulse is delivered while the output capacitor is charging (see paragraph 87, ln. 1-4 and Figure 5).

12. Regarding claims 5 and 15, Casavant discloses a feedback loop in Figure 5 that determines whether one or more shock pulses applied to the heart result in a termination of the ventricular fibrillation. If the fibrillation is still detected, the device of Casavant evaluates whether shock or pacing is required and delivers the specified therapy. Diaphragmatic pacing pulses are applied if it is determined that a previous shock pulse failed to terminate the ventricular fibrillation (see Figure 5).

13. Regarding claims 6, 10, and 16, Casavant discloses that a diaphragmatic pacing pulse may be delivered during a ventricular refractory period of a ventricular sense (see paragraph 36, ln. 16-19).

14. Regarding claims 7 and 17, Casavant discloses that the controller begins charging an output capacitor of the ventricular shock channel when ventricular fibrillation is detected and a diaphragmatic pacing pulse is delivered while the output capacitor is charging (see paragraph 87, ln. 1-4 and Figure 5), and a diaphragmatic

pacing pulse may be delivered during a ventricular refractory period of a ventricular sense (see paragraph 36, ln. 16-19).

15. Regarding claim 12, Casavant discloses that the diaphragmatic pacing is delivered as pacing pulses to the phrenic nerve (see paragraph 36, ln. 16-19).

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stahmann et al. (U.S. 2005/0043772) which discloses a method for detecting and treating disordered breathing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

TKH